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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,522	02/11/2002	Cristian L. Achim	214001-00823-1	5288

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EXAMINER
NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
1647	6

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/073,522	ACHIM ET AL.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 4, 5, 6, 14, 15, and 17 (each in part), drawn to a method for treating a neurodegenerative illness in a patient comprising culturing neuronal cells *in vitro* with an effective amount of an **organic compound** having an affinity for immunophilins, transplanting said cultured neuronal cells into said patient, and further comprising administering to said patient an effective amount of said compound **during transplantation** of said neuronal cells, classified dependent upon organic compound structure.

II. Claims 1, 2, 4, 8, 9, 10, 11, 14, 15, and 17 (each in part), drawn to a method for treating a neurodegenerative illness in a patient comprising culturing neuronal cells *in vitro* with an effective amount of a **growth factor** having an affinity for immunophilins, transplanting said cultured neuronal cells into said patient, and further comprising administering to said patient an effective amount of said growth factor **during transplantation** of said neuronal cells, classified dependent upon organic compound structure.

III. Claims 1, 3, 4, 5, 7, 14, 16, and 17 (each in part), drawn to a method for treating a neurodegenerative illness in a patient comprising culturing neuronal cells *in vitro* with an effective amount of an **organic compound** having an affinity for immunophilins, transplanting said cultured neuronal cells into said patient, and further comprising administering to said patient an effective amount of said

organic compound **after transplantation** of said neuronal cells, classified dependent upon organic compound structure.

IV. Claims 1, 2, 4, 8, 9, 10, 11, 12, 13, 14, 15, and 17 (each in part), drawn to a method for treating a neurodegenerative illness in a patient comprising culturing neuronal cells *in vitro* with an effective amount of a **growth factor** having an affinity for immunophilins, transplanting said cultured neuronal cells into said patient, and further comprising administering to said patient an effective amount of said growth factor **after transplantation** of said neuronal cells, classified dependent upon organic compound structure.

V. Claims 18-20, drawn to a method of improving the survival of neuronal cell transplants in a patient, classification dependent upon compound structure.

VI. Claims 21-23, drawn to a method of improving neurite extension and integration of neuronal cell transplants in a patient, classification dependent upon compound structure.

VII. Claims 24-25, drawn to a method of improving neurite proliferation, neurite extension, and neuronal survival of second trimmest human fetal neuronal cell transplants, classification dependent upon compound structure.

VIII. Claims 26-27, drawn to a method of decreasing gliosis of second trimmest human fetal neuronal cells, classification dependent upon compound structure.

IX. Claim 28, drawn to a second trimester human fetal neuronal cell that has been cultured with at least one compound having an affinity for immunophilins, classification dependent upon compound structure.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, II, III, IV, V, VI, VII, and VIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of culturing neuronal cells *in vitro* with an effective amount of an organic compound and administering said compound to a patient during transplantation, which is not required by any of the other Inventions. Invention II requires search and consideration of culturing neuronal cells *in vitro* with an effective amount of a growth factor and administering said growth factor to a patient during transplantation, which is not required by any of the other Inventions. Invention III requires search and consideration of culturing neuronal cells *in vitro* with an effective amount of an organic compound and administering said compound to a patient after transplantation, which is not required by any of the other Inventions. Invention IV requires search and consideration of culturing neuronal cells *in vitro* with an effective amount of a growth factor and administering said growth factor to a patient after transplantation, which is not required by any of the other Inventions. Invention V requires search and consideration of improving the survival of neuronal cell transplants in a patient, which is not required by any of the other Inventions. Invention VI requires search and consideration of improving neurite extension and integration of neuronal cell transplants in a patient, which is not required by any of the other Inventions. Invention VII requires search and consideration of improving neurite

proliferation of neuronal cell transplants in a patient, which is not required by any of the other Inventions. Invention VIII requires search and consideration of decreasing gliosis, which is not required by any of the other Inventions.

4. Inventions I and each of I, II, III, IV, V, VI, VII, and VIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. The cells of Invention IX can be used to for a cell based screening method of neurotrophic factors.

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. FK506

b. Rapamycin

c. Cyclosporin A

d. FK-520

e. FK-523

f. 15-O-DeMe-FK-520

g. (4R)-[(E)-L-butenyl]-4,N-dimethyl-L-threonine

h. GPI-1046

i. V-10,367

j. Biological equivalents thereof

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 5, 6, and 7 are generic.

7. If applicant selects either Inventions I or III, one species from the organic compound must be chosen to be fully responsive.

8. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. This application contains claims directed to the following patentably distinct species of the claimed invention:

k. Nerve growth factor (NGF)

l. Hepatocyte growth factor (HGF)

m. Brain-derived neurotrophic factor (BNDF)

n. Insulin growth factor (IGF)

o. gIGF-1

p. Acidic fibroblast growth factor (aFGF)

q. Basic fibroblast growth factor (bFGF)

r. Platelet-derived growth factor (PDGF)

s. Ciliary neurotrophic factors (CNTF)

t. Leukemia inhibitory factor

u. Glial cell line-derived neurotrophic factor (GDNF)

v. Neurotrophin-3 (NT-3)

w. Neurotrophin-4 (NT-4)

x. Biological equivalents thereof

11. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 9, 11, and 13 are generic.

12. If applicant selects either Invention II or IV, one species from the growth factor group must be chosen to be fully responsive.

13. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

14. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Nichols, Ph.D. whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Elizabeth C. Kemmerer

CJN
December 18th, 2002

ELIZABETH KEMMERER
PRIMARY EXAMINER